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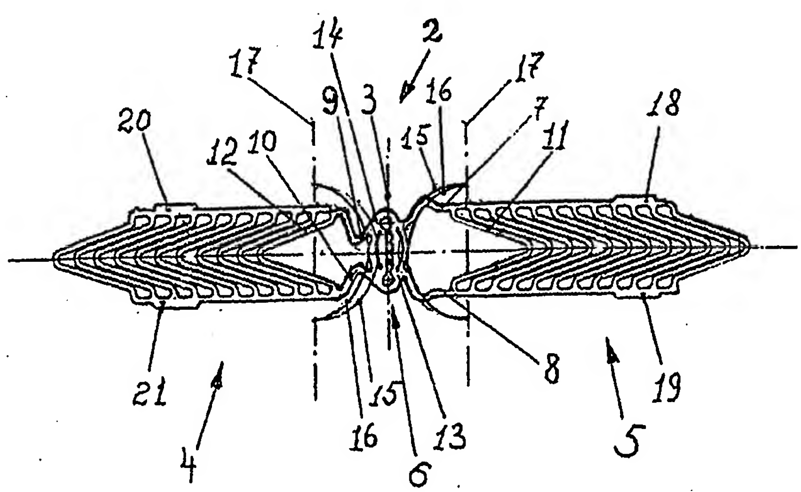

(57) Abstract

The flat stencil (2) of the future stent constructive elements is divided into two parts (4, 5) by the central vertical axis (3). In the middle part of the stencil (2) a cross-member (6) with the connecting carriers (7, 8, 9, 10) is executed to be fastened to the winding outlines peripheral parts (11, 12) neighboring with it. The cross-member (6) can be executed in several variants. Upon the expansion of the stent, the cross-member (6) with the connecting carriers (7, 8, 9, 10) covers the pair vessels carina area safely enough, held by the stent branches semi-circles (12). Some of the semi-circles (12) sections of the stent branches outlet outward sides (in relation to the blood flow) are relatively rigid bands width, the other semi-circles (12) sections of the stent branches outward sides are executed as the weakened ones (75) at the expense of decreasing the width of the relatively rigid bands, fastening reinforced and weakened semi-circles (12) between themselves. This creates "bell-mouthed" effect on the stent end faces upon its placing in a vessel.

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A MODULAR BIFURCATED INTRALUMINAL STENT

Field and Background of the Invention

The present invention relates generally to medical technology, particularly, to expandable cardiovascular stents which are intended for the radial arterial lumen recovery with subsequent restoring of the normal blood flow.

The appearance of the coronary vessels stenosis as a mechanical cause is determined by a rather complicated hemodynamics of the blood flow. Along with this the unfavorable peculiarities of the hemodynamics begin to manifest themselves especially clearly in case of the pathological changes in the organism. In places of the turbulent blood flows and the turbulences, with the decreased circulation and stagnant sections accompanying them, the zones of risk appear. In these sections the appearance of stenosis is most likely.

The said zones of risk appear at places of rather sharp blood flow change. These places could be marked as follows: the carina area of the pair vessels the unfavorable influence intensivity of which depends, to a considerable degree, upon their geometry, i.e. how "sharp" or "blunt" are such carina areas (for details see the book Heart Disease by E. Braunwald. A Textbook of Cardio-vascular Medicine, Vol. 1, 1992, Ch. 9, p. 249, Figs. 9-17 A,B; 9-18 B). As is seen from the clinical practice the most dangerous pathogen of stenosis are precisely the carina areas of the pair vessels. It is particularly shown by the fact that the probability of the stenosis occurrence in the pair vessels is increasing to a considerable degree upon the stenting of the main vessel (see M. Kutryk and P. Serruys Coronary Stenting. Current Perspectives, 1998), when edge effects from

area began summing together. In all known cases a special requirement about the straight preservation of perpendicularity to the axis of stent end faces is not advanced. It is supposed that in the majority of cases this is achieved automatically in accordance with the stent design peculiarities. At the same time, according to the clinical practice data, the non-perpendicularity of the stent end faces increase, to a considerable degree, the possibility of restenosis appearance due to the violation of the blood flow hemodynamics edge effects symmetry. However, even given the symmetry of turbulences at the stent outlet, the danger of restenosis is not eliminated, since the stent wall thickness is big enough in relation to the vessel diameter.

Thus, notwithstanding the deployment or not deployment of the stent in the main vessel, the protection of the carina area upon the manifestation of stenosis is necessary and, particularly, in case of the appearance of a lesion directly in the pair vessels carina area. And for the restenosis prophylactics it is desirable, along with preserving the stent end faces perpendicularity, to decrease the thickness of its walls.

Prior Art

According to the data of the specialized and patent literature, there is no information about the directed protection of the pair vessels carina area, while the covering of the carina area, if it is present, is done by a mere chance during the deployment of the stents either in the pair vessels (proximal LAD and diagonal D) or in these vessels and the main vessel. Leaving the pair vessels carina area uncovered could, to a considerable degree, be the cause of the restenosis of the region of vessels under examination.

Below are the clinical-technical examples of the plaque pathological formation liquidation and of the coronary vessel lumen restoration prophylactics (see Fig. 1A, Fig. 1B and Fig. 2). The extensiveness of intracoronary intervention is determined by a diagnosed degree of the vessels lesion. With the presence of plaques in the LAD and D branches the stents are placed in them only (Fig. 1A) apparently considering that the injury of the pair vessels carina area does not by itself lead to the occlusion of vessels in the blood flow system. However, the possible separation of the carina area plaque can, naturally, provoke a critical situation in the patient's condition. With the more extensive vessel lesion, the additional stent installation in the main vessel is necessary and is performed, practically butt-joined to the stents implanted in the pair vessel: branches LAD and D (Fig. 1B). However, such a procedure technique in no way eliminates the problem of stenosis occurrence directly in the very carina area. Moreover, the edge hemodynamics effects at the stent end face, placed in the main vessel, can only aggravate the described unfavorable situation. Thus, the described procedures of the intravascular intervention do not give any protection guarantee from the consequences of stenosis appearing directly in the pair vessels carina area: the carina area remains unprotected. Another method of pair vessels carina area full coverage, known in the clinical practice as Colombo "Inverted Y" technique, is described (Fig. 2). In this case, alongside the general clinical stenting technology peculiarities there takes place a rather accidental covering of the pair vessel carina area by a carrier (1) connecting the branches of the two stents. The covering of the pair vessels carina area by the carrier (1) is a favorable clinical factor in the sense of keeping the already formed plaque in the carina area and only in the case when the carrier (1)

efficiently covers this plaque. Besides, the sufficiently thin carrier (1) is not able to prevent the possible plaque growth, including that over the carrier (1). The drawback of covering by thin carrier (1) the pair vessels carina area is especially vividly seen in the presence of as though relatively spreading extended cross sizes of the carina area (when it is practically impossible to determine its width), as is shown in Figs. 9-17 A,B in the said book Heart Disease by E. Braunwald, p. 249.

This is why the Colombo "Inverted Y" technique system also can not be considered as efficient enough for the prevention of the pair vessels stenosis consequences.

Summary of the Invention

The purpose of the invention is to create a double stent single design, in which, alongside the performed common requirements, the reliable protection of pair vessels carina area is ensured notwithstanding the complexity of the technological and design solution of the previously conditioned clearance limit fulfilled on the the sheet metallic blank stencil.

The purpose of the invention is also to lower the turbulent events in the blood flow at the stent end faces.

The said purpose is achieved by the fact that in the Sheet Expandable Pair Stent with the "VB" Effect the constructive elements of the two branches for the pair vessels of which, preliminary formed as the stencils on the surface of just on one thin sheet metallic blank containing periodically repeating different forms of winding outlines fastened by the sections of the relatively rigid bands along the longitudinal axes with a possibility of forming breaks for achieving the flexibility of the future stent determined in advance, whereas the symmetry axes of the said

winding outlines along the said stencils are situated in one line, while between the future stent contiguous lateral sides a mesh structure, a cross-member, is situated, fastened by the connecting carriers, two from the end side, to the peripheral constructive elements parts of the joining winding outlines.

In the said Sheet Expandable Pair Stent with "VB" Effect the clearance limits of the said mesh structure, a cross-member, are executed after the slotted plate form as a kind of different configurations, in which the ratio between the slotted area and the metallic area is 15%...30%, whereas the greater value of this ratio corresponds to the greater width of the said slotted plate.

In the said Sheet Expandable Pair Stent with the "VB" Effect the stencil of which includes the said periodically repeating winding outlines, fastened by the said sections of the relatively rigid bands along the longitudinal axis with the break from the side of one relatively rigid band, along the entire said stencil symmetry axis of the said winding outline situated in one line, while the said future stent branches are formed by their fold for a 90° angle, one in relation to another, at the place of the said break of the said relatively rigid band, whereas the geometrical form of the relatively rigid band section, situated oppositely to the said break of the said relatively rigid band is executed as a complicated one, or mainly in a shape of a triangle with a hole.

In the said Sheet Expandable Pair Stent with the "VB" Effect, in which the said relatively rigid bands sections fastening the third, fourth, fifth and sixth winding outlines from the outward sides of the future stent branches stencils are executed as the reinforced ones at the expense of increasing the width of each one for no less than 5%, while the said sections of the relatively rigid bands fastening the first,

second and third winding outlines are executed as the weakened ones at the expense of decreasing the width of each one of them for no less than 5%.

In the said Sheet Expandable Pair with the "VB" Effect the length of the said mainly four winding outlines of the said stencil, the last from the stent end faces, is increased: the first two in $(1 + k\frac{S}{0.5D})$ times, and the following two in $(1 + k\frac{S}{D})$ times, where S - the thickness of the stent stencil metallic blank; D - the diameter of the stent implanted in a vessel; k - a coefficient, depending on the vessel wall thickness, with a possibility of change from 1 to 2, whereas upon the expansion of the stent in a vessel, the width of the said winding outlines constructive elements decreases correspondingly: the first two in $(1 + k\frac{S}{0.5D})$ times, and the following two in $(1 + k\frac{S}{D})$ times.

The method of implantation of the said Sheet Expandable Pair Stent with the "VB" Effect , in which the kissing balloons of the guiding catheter with the branches of the said stent are shifted, one in relation to another, in an axial direction for a value of the said mesh structure, a cross-member, width with the connected carriers are located in such a way that the surface of the said mesh structure will be the continuation of the stent surface, turned to the said kissing balloons contact line.

As a result, the proposed stent model allows to cover the pair vessels carina area lesion safely enough, excluding the possibility of plaque remnants migration into the vessels lumen, while a constructive form of the stent branches outlet outward sides secures the perpendicularity of stent end faces at the expense of reinforcing the winding outlines (semi-circles), starting with the third from the stent end faces and the formation of the "bell-mouth" right on the stent end face at the expense of

additional expansion of the two relatively weakened winding outlines (semi-circles), the first from the stent end faces. Such a form of the stent branches exit outward sides improves, naturally, the blood flow hemodynamics at the outlet from the stent, and as a consequence, is contributing to the decrease in the restenosis risk.

Brief Description of the Drawings

This invention is herein described with the help of examples and references to the accompanying drawings, wherein:

Fig. 1A shows the "Y" technique for the treatment of bifurcation lesions. Two stents are implanted from the osmium of both branches.

Fig. 1B shows the same as in Fig. 1A, but a stent crimped on two balloons is advanced to both branches. Alternatively, the third stent can be mounted on one balloon with a final kissing balloon expansion.

Fig. 2 shows the Colombo "Inverted Y" technique for the treatment of bifurcation lesions. Three stents are mounted on suitably long balloons, one stent being mounted on both balloons. The entire "bifurcation stent" is placed in one manoeuvre.

Fig. 3 shows a general view of the constructive elements flat stencils of the future stent that is divided into two parts by the central vertical axis. Each part is intended for forming a stent branch of one of the pair vessels. In the stencils' middle part a mesh structure, a cross-member, with connecting carriers for the fastening of stent branches, is shown. The right and left parts of the mesh structure with connecting carriers are shown in two variants: I and II.

Fig. 4 shows schematically the stereoscopic picture of the constructive elements of the stent located in the pair vessels carina area.

Fig. 5 shows a future stent constructive elements flat stencil with the simplified mesh structure, a cross-member.

Fig. 6 shows schematically the beginning of the necessary fold of the future stent branches with the semi-circles, calibrated in advance, prior to the locating of the stent on a pair of the kissing balloons. In this case, the mesh structure, a cross--member, preliminary folded to the 90° angle, is shown as a plate.

Fig. 7 shows schematically the semi-circles cross-section, connected by the simplified mesh structure, a cross-member.

Fig. 8 shows schematically the kissing balloons with the stent branches, one in relation to another, and the free enough location of the mesh structure, a cross--member, overstepping beyond the contact limits of the kissing balloons.

Fig. 9 shows a fragment of the constructive elements flat stencil, characteristic of the stent both branches outlet sides (in relation to the blood flow). There are seen the reinforced and weakened semi-circles sections correspondingly at the expense of increasing or decreasing the width of the section of the relatively rigid bands, fastening the semi-circles between themselves.

S - the thickness of the stent stencil metallic blank.

Fig. 10 shows schematically (a side view) the semi-circles of the stent fragment according to the stencil in Fig. 9.

Fig. 11 shows schematically the stent fragment according to Fig. 10, where the semi-circle with weakened part of the relatively rigid band is combined with the next semi-circle, thus securing the stent end face perpendicularity to the stent longitudinal axis.

Fig. 12 shows schematically how the inflation of the balloon end part leads to the

additional deformation of the stent end face semi-circles, thus ensuring the "bell--mouthed" effect at the blood flow outlet.

Specific Description

Fig. 3 shows a general view of the flat stencil (2) of the constructive elements of the future stent that is divided into two parts (4, 5) by the central vertical axis (3). Each part (4, 5) is intended for the formation of the stent branch of one of the pair vessels. In the stencil's (2) middle part the mesh structure, cross-member (6), with the connecting carriers (7, 8, 9, 10) for fastening to the peripheral parts of the neighboring winding outlines (11) and (12) are shown. The right and left parts of the mesh structure (6) with the connecting carriers (7, 8, 9, 10) are shown in two variants: pos. (13) and pos. (14).

In Fig. 3 the conditional outlines of the future stent semi-circles (15), as well as the projections (16) on the drawing plane of these semi-circles that are already present in the pair vessels, are marked. The semi-circles (15) projections (16) are shown rather conditionally and can be considered as a result of the pair vessel branches spread at the 30° - 60° angle. Pos. (17) marks the axes of the conditional semi-circles (15) pictures and their projections (16) on the drawing plane. It is seen from Fig. 3 that the mesh structure (6) lateral parts do not touch the semi-circles (15) projection (16), i.e. the mesh structure (6) does not superimpose on the neighboring semi-circles. Variants I and II (pos. 13 and 14) of the mesh structure (6) could be distinguished by a great diversity, i.e. not to be limited by the given views in pos. (13, 14), simply as an example of the possible diversity. However, the placement of the connecting carriers (7, 8,) and (9, 10) pairs in variants I and II essentially differs as is shown below.

V a r i a n t I (pos. 13). It is seen from Fig. 3 that though the semi-circle conditional outline (15) superimposes on the mesh structure (6) and the carriers (7, 8), that does not take place with semi-circle projection (16). As a result the superimposing of the constructive elements (11, 7, 12, 8) against each other during the deployment of the stent into a vessel is not observed.

V a r i a n t II (pos. 14). The connecting carriers (9, 10) have a more winding form, securing good compensational properties of their extent. This is an important circumstance in case of the limited information about the form structure and geometrical sizes of the pair vessels carina area. It is seen from Fig. 3 that though the mesh structure (6) does not superimpose on the neighboring semi-circle (12) projection (16), the connecting carriers (9) and (10) cross the projection (16) and, consequently, can superimpose on the semi-circle (12) elements. This should not be considered as a serious construction drawback, since while calibrating of the stent semi-circles the constructive elements (9, 10, 12) are located on one surface and with the final expansion of in the vessel, the stent branches of the connecting carriers (9, 10) joining part will also be tightly pressed to the vessel wall. However, this could in general be avoided if variant I for the cases of "sharp" pair vessels carina area is recommended, as is shown in Fig. 9-18 B in the said book Heart Disease by E. Braunwald, p. 249.

Variant II should be recommended for the cases of "blunt" pair vessels carina area, as is illustrated in Fig. 9-17 B in the same book. In this case the semi-circle (12) projection (16) practically coincides with axis (17) - the spread of the pair vessels branches is closed to 180° - and the superimposition of the connecting carriers (9, 10) and semi-circle (12) will not take place.

Pos. (18, 19) and pos. (20, 21) mark the reinforcement of the sections in relation to the rigid bands, necessary for obtaining the "bell-mouthed" effect at the outlet of the blood flow from the stent branches.

Since the branches (4, 5) have one common axis, the preliminary calibration of both branches semi-circles is done simultaneously, so that the mesh structure (6) with connecting carriers (7, 8, 9, 10) and the neighboring semi-circles (11, 12) will be parts of one and the same surface. Then the stent branches (4, 5) are folded around the central vertical axis (3) until the axes of branches (4) and (5) become parallel before their deployment on the pair of kissing balloons. In this case the kissing balloons with stent branches (4, 5) are shifted, one in relation to another, in the axial direction to the value of the mesh structure (6) width with the connecting carriers (7, 8, 9, 10), so that the mesh structure (6) becomes the continuation of the stent surface turned to the kissing balloons contact line. As a result, the possibility of crumpling the mesh structure (6) by the balloons, and at the final placement of the stent branches (4, 5) closely superimpose the mesh structure (6) upon the pair vessels carina area with the help of the connecting carriers (7, 8, 9, 10).

In Fig. 4 is schematically shown the stereoscopic picture of the constructive elements of the stent located in the pair vessels carina area. The main vessel is marked by pos. (22), the pair vessels (proximal LAD and diagonal D) - by pos. (23, 24), the pair vessels carina area - by pos. (25). It is seen from Fig. 4 how the mesh structure (26) with the connecting carriers (27, 28, 29, 30) covers the pair vessels (23, 24) carina area (25) and is kept fast by the stent branches (33, 34) semi--circles (31, 32). It is also seen from Fig. 4 that the mesh structure (26) form

variations can protect the pair vessels carina area safely enough.

Fig. 5 shows a future stent constructive elements flat stencil (35) with the simplified mesh structure (36), a cross-member, for the pair vessels carina area. It is also here that the reinforcements of the relatively rigid bands, necessary for producing the "bell-mouthed" effect at the blood flow outlet from stent branches are marked by the pos. (37, 38) and pos. (39, 40). Fig. 5 shows the winding outlines (41, 42), including also those of the future stent semi-circles adjoining the mesh structure (36), which have another form than that described in Fig. 3.

Fig. 5 shows the winding outlines (41, 42) of the Z-shaped stencil form, while Fig. 3 shows the winding outlines of the V-shaped stencil form. Such a variety of the stencil winding outline within the limits of one patent is introduced intentionally, so as to show the independence of the proposed technical solutions from the future stent semi-circles form. It is supposed that at the state when the future stent branches (43, 44) stencil longitudinal axes are in one line, the preliminary simultaneous calibration of both branches is performed prior to their mounting on a pair of kissing balloons (the kissing balloons are not shown in Fig .3 and Fig. 5). In this case, it is desirable that the winding outlines (41, 42), closest to the mesh structure (36), were located on one and the same surface upon the stent branches (43, 44) calibration. Alongside the stent branches (43, 44) semi-circles calibration the folding of the mesh structure at the 90° angle is performed.

By pos. (45) a break of the relatively rigid band on the stencil (35) executed opposite the mesh structure (36) and necessary for the folding of the future stent branches (43, 44) and the stent consequent mounting on the kissing balloons is marked. The single break (45) of the relatively rigid band does not exclude the

possibility of executing also other breaks of the relatively rigid band (not shown in Fig. 3 and Fig. 5), contributing to the increase in stent branches flexibility.

By pos. (46, 47) and pos. (48, 49) the sections of the future stent branches (43, 44) relatively rigid bands on the stencil (35) are marked.

Fig. 6 shows schematically the beginning of the necessary branches (50, 51) fold of the future stent, with the preliminary calibrated semi-circles (52, 53), prior to the mounting of the stent on a pair of the kissing balloons. In this case, the mesh structure, a cross-member, for the pair vessels carina area, preliminary folded at the 90° angle, is presented in projection as a kind of a plate (54).

Pos. (55, 56) and pos. (57, 58) mark the sections of the stent branches (50, 51) relatively rigid bands. The sections (55, 57) are turned around the points (59, 60) following the course arrows (61, 62) for the 90° angle. Then the stent is mounted on a pair of kissing balloons. In this case, the kissing balloons with the stent branches (50, 51) are shifted, one in relation to another, in the axial direction on a value of the mesh structure width in such a way, as to make the mesh structure a continuation of the stent surface, turned to the kissing balloons contact line. As a result, the possibility of crumpling the mesh structure by the balloons is excluded and upon the final stent placement the branches (50, 51) superimpose the mesh structure on the pair vessels carina area.

Fig. 7 shows schematically the cross-section of the semi-circles (63, 64) connected by the simplified mesh structure (65). In this case also, appoximalety shown is the "A" size width of the pair vessels carina area width taking into account its scale relationship with the stent constructive elements. As seen from Fig. 7 the partial covering of the pair vessels carina area by the semi-circles (63, 64) of the stent

branches is taking place. Let us notice that in case of necessity the width of the mesh structure (65) could be increased.

Fig. 8 shows schematically the kissing balloons (66, 67), shifted one in relation to another, with the stent branches (68, 69), and also the free location of the mesh structure (70), passing beyond the contact limits of the balloons. Upon the final placement of the stent branches (68, 69) into the pair vessels, the mesh structure (70) straightens, covering the carina area as has been already described in Fig. 3 and Fig. 6.

Fig. 9 shows the future stent constructive elements stencil (71) fragment, which is characteristic for the outlet outsides (in relation to the blood flow) of both stent branches for pair vessels. There are seen the reinforced (72, 73, 74) and weakened (75) fragments of the semi-circles correspondingly, at the expense of increasing (76, 77) and decreasing (78, 79) the width of the relatively rigid bands, fastening the said reinforced and weakened semi-circles among themselves.

Fig. 10 shows schematically (side view) stent fragment semi-circles according to the stencil in Fig. 9. It is seen that the reinforced semi-circles (80, 81, 82) are fastened by the more wide sections (83) of the relatively rigid bands (84) - the side view shows only one relatively rigid band - as compared with the sections, fastening the rest of the stent semi-circles. The weakened semi-circle (85) is fastened by the less wide sections (86) of the relatively rigid band (84).

Fig. 11 shows schematically the stent fragment in accordance with Fig. 10, where the semi-circle (87) with the relatively rigid band weakened part (88) (corresponds to pos. 85, 86 in Fig. 10) is combined with the neighboring semi-circle (89), thus securing the perpendicularity of the stent end face to the stent longitudinal axis

upon the expansion. At the expense of the two constructive elements (88), the stent outlet circle, consisting of semi-circles (87, 89) can have a slightly greater diameter than that corresponding to the other stent branch semi-circles. It is natural that the partially compressed on the guiding balloon stent semi-circles, together with the semi-circles (87, 89) of the outlet circle, have one and the same diameter necessary for advancing the stent in a vessel.

Fig. 12 shows schematically the final stage of the stent placement in a vessel upon the maximal inflation of the balloon (90). It is seen that the balloon part passing beyond the stent branch limits, while not meeting with the resistance from the semi-circles side, inflates to some greater diameter, correspondingly expanding to some greater diameter a circle, consisting of semi-circles (91, 92), which corresponds to pos. (87, 89) in Fig. 11, integrating into a vessel wall somewhat more than the stent neighboring semi-circles. It is this very fact that creates the "bell-mouthed" effect at the blood flow outlet and, as a consequence, decreases the possibility of turbulences occurrence and thus ensures the conditions for the more adequate hemodynamics in a vessel (93).

Pos. (94) in Fig. 12 marks the polymer tube of the guiding catheter, while pos. (95) - the guide wire.

The "bell-mouth", formed by the semi-circles, the last from the stent end faces, could be obtained by the insignificant increase in the length of the corresponding last winding outlines of the flat stencil. In this case, upon the expansion of the stent in a vessel, the width of the said winding outlines constructive elements will be decreased one correspondingly, that could contribute to the decrease in the deformation resistance of the said semi-circles, the last from the stent end face, and

to more strict perpendicularity of the stent end faces to the longitudinal axis.

Let us separately notice that the described producing of the "bell-mouthed" effect could be performed in the simple stents not only at the outlet, but also at the inlet of the blood flow that should improve the general hemodynamics, i.e. the remote consequences of the intravascular intervention.

Thus, the design of the stent possessing the substantial advantages in comparison with the known ones is presented. The possibility of placing the cross-member in the pair vessels carina area, that is executed in a shape of the mesh structure of any favorable form, and the use of namely the four connecting carriers allows more reliably to cover the pair vessels carina area lesion independently of the cross-member clearance limits: four connecting carriers make the system of this cross-member fastening statically determined.

The execution of the "bell-mouth" at the blood flow inlet and outlet from the stent makes the hemodynamics in a vessel more favorable, thus decreasing the risk of restenosis.

What is claimed is:

1. The Sheet Expandable Pair Stent with the "VB" Effect for insertion in a lumen of a vessel of living being, comprising:

- constructive elements of two branches for the pair vessels, preliminary formed as stencils on the surface of just on one thin sheet metallic blank, containing the periodically repeating winding outlines variants diverse in their forms, fastened by the relatively rigid bands sections along the longitudinal axes with the possibility of forming breaks for the achievement of the future stent flexibility, whereas the symmetry axes of the said winding outlines along the said stencils are located in one line, and between the adjoining lateral sides of the future stent said branches the mesh structure, a cross-member, is located, fastened to the constructive elements peripheral parts, joining the winding outlines, by the connecting carriers, two from each side;

- the clearance sizes of the said mesh structure, a cross-member, are executed in accordance with the pair vessels carina area geometrical sizes;

- the said mesh structure, a cross-member, is executed after the slotted plate form, as a kind of different configurations, in which the ratio between the slotted area and the metallic area comprises 15%...30%, whereas the greater value of this ratio corresponds to the greater width of the said slotted plate.

2. The Sheet Expandable Pair Stent with the "VB" Effect as in claim 1, the stencil of which includes the said periodically repeating winding outlines, fastened by the said relatively rigid bands sections along the longitudinal axis with a break from the side of the one relatively rigid band, along the entire said stencil symmetry axis of the said winding outlines are located in one line, while the said future stent

branches are formed by the fold at the 90° angle, one in relation to another, in a place of the said relatively rigid band break, whereas the geometrical form of the relatively rigid band section, appositively located to the said relatively rigid band break, is executed in a complicated form, or mainly in a shape of a triangle with a hole.

3. The Sheet Expandable Pair Stent with the "VB" Effect as in claims 1, 2, in which the said relatively rigid bands sections, fastening the third, fourth, fifth and sixth winding outlines from the outward sides of the future stent branches stencil, are executed as the reinforced ones at the expense of increasing the width of the each one of them for no less than 5%, while the said relatively rigid bands sections, fastening the first, second and third winding outlines are executed as the weakened ones at the expense of decreasing the width of the each one of them for no less than 5%.

4. The Sheet Expandable Pair Stent with the "VB" Effect as in claims 1, 2, 3, in which the length of the said mainly four winding outlines of the said stencil, the last from the stent end faces, is increased: the first two in $(1 + k\frac{S}{0.5D})$ times, and the following two in $(1 + k\frac{S}{D})$ times, where S - the thickness of the stent stencil metallic blank; D - the diameter of the stent implanted in a vessel; k - a coefficient, depending on the vessel wall thickness, with a possibility of change from 1 to 2, whereas upon the expansion of the stent in a vessel, the width of the said winding outlines constructive elements decreases correspondingly: the first two in $(1 + k\frac{S}{0.5D})$ times, and the following two in $(1 + k\frac{S}{D})$ times.

5. The Sheet Expandable Pair Stent with the "VB" Effect as in claims 1, 2, 3, 4, in which the kissing balloons of the guiding catheter with the said stent branches are

shifted, one in relation to another, into the axial direction for a value of the width of the said mesh structure, a cross-member, with the connecting carriers in such a way that the said mesh structure surface was made the continuation of the stent surface turned to the said kissing balloons contact line.

AMENDED CLAIMS

[received by the International Bureau on 17 August 1999 (17.08.99);
original claims 1-5 replaced by amended claims 1-6 (3 pages)]

1. A Modular Bifurcated IntraluminaL Sheet Stent with the "Bell-Mouthed" Effect for insertion in a lumen of a vessel of living being, comprising:

- constructive elements of two branches for the pair vessels, preliminary formed as stencils on the surface of just on one thin sheet metallic blank, containing the periodically repeating winding outlines variants diverse in their forms, fastened by the relatively rigid bands sections along the longitudinal axes with the possibility of forming breaks for the achievement of the future stent flexibility, whereas the symmetry axes of the said winding outlines along the said stencils are located in one line, and between the adjoining lateral sides of the future stent said branches the mesh structure, a cross-member, is located, fastened to the constructive elements peripheral parts, joining the winding outlines, by the connecting carriers, two from each side;

- the clearance sizes of the said mesh structure, a cross-member, are executed in accordance with the pair vessels carina area geometrical sizes;

- the said mesh structure, a cross-member, is executed after the slotted plate form, as a kind of different configurations, in which the ratio between the slotted area and the metallic area comprises 15%...30%, whereas the greater value of this ratio corresponds to the greater width of the said slotted plate.

2. A Modular Bifurcated Intraluminal Sheet Stent with the "Bell-Mouthed" Effect as in claim 1, the stencil of which includes the said periodically repeating winding outlines, fastened by the said relatively rigid bands sections along the longitudinal axis with a break from the side of the one relatively rigid band, along the entire

said stencil symmetry axis of the said winding outlines are located in one line, while the said future stent branches are formed by the fold at the 9 angle, one in relation to another, in a place of the said relatively rigid band break, whereas the geometrical form of the relatively rigid band section, appositively located to the said relatively rigid band break, is executed in a complicated form, or mainly in a shape of a triangle with a hole.

3. A Modular Bifurcated Intraluminal Sheet Stent with the "Bell-Mouthed" Effect as in claims 1, 2, in which the said relatively rigid bands sections, fastening the third, fourth, fifth and sixth winding outlines from the outward sides of the future stent branches stencil, are executed as the reinforced ones at the expense of increasing the width of the each one of them for no less than 5%, while the said relatively rigid bands sections, fastening the first, second and third winding outlines are executed as the weakened ones at the expense of decreasing the width of the each one of them for no less than 5%.

4. A Modular Bifurcated Intraluminal Sheet Stent with the "Bell-Mouthed" Effect as in claims 1, 2, in which the length of the said relatively rigid bands sections, fastening the first and second winding outlines from the outward sides of the future stent branches stencil, is calculated in such a way that upon the expansion of the said future stent the said constructive elements form an edge face circle.

5. A Modular Bifurcated Intraluminal Sheet Stent with the "Bell-Mouthed" Effect as in claims 1, 2, 3, 4 in which the length of the said mainly four winding outlines of the said stencil, the last from the stent end faces, is increased: the first two in $(1 + k \frac{S}{0{,}5D})$ times, and the following two in $(1 + k \frac{S}{D})$ times, where S - the

thickness of the stent stencil metallic blank; D - the diameter of the stent implanted in a vessel; k - a coefficient, depending on the vessel wall thickness, with a possibility of change from 1 to 2, whereas upon the expansion of the stent in a vessel, the width of the said winding outlines constructive elements decreases correspondingly: the first two in $(1 + k \frac{S}{0,5D})$ times, and the following two in $(1 + k \frac{S}{D})$ times.

6. A Modular Bifurcated Intraluminal Sheet Stent with the "Bell-Mouthed" Effect as in claims 1, 2, 3, 4, 5, in which the kissing balloons of the guiding catheter with the said stent branches are shifted, one in relation to another, into the axial direction for a value of the width of the said mesh structure, a cross-member, with the connecting carriers in such a way that the said mesh structure surface was made the continuation of the stent surface turned to the said kissing balloons contact line.

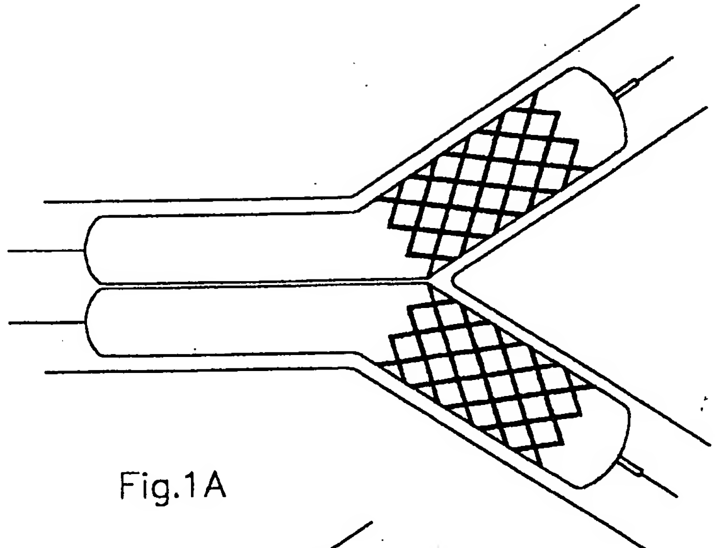

Fig.1A

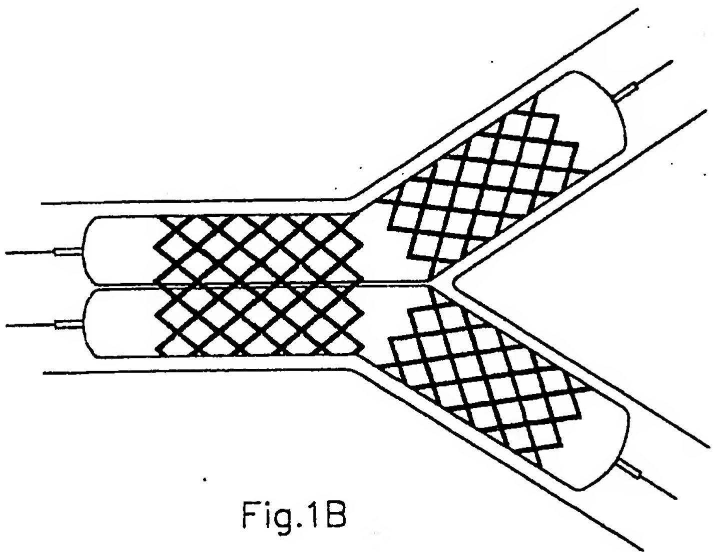

Fig.1B

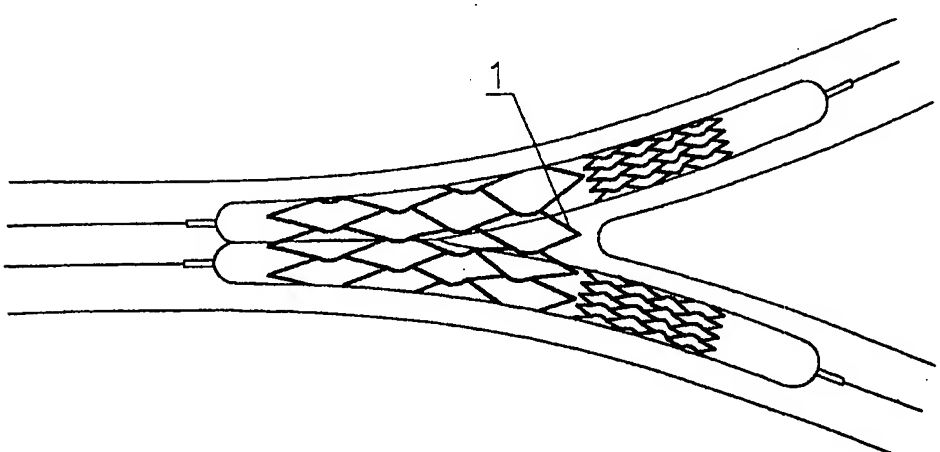

Fig.2

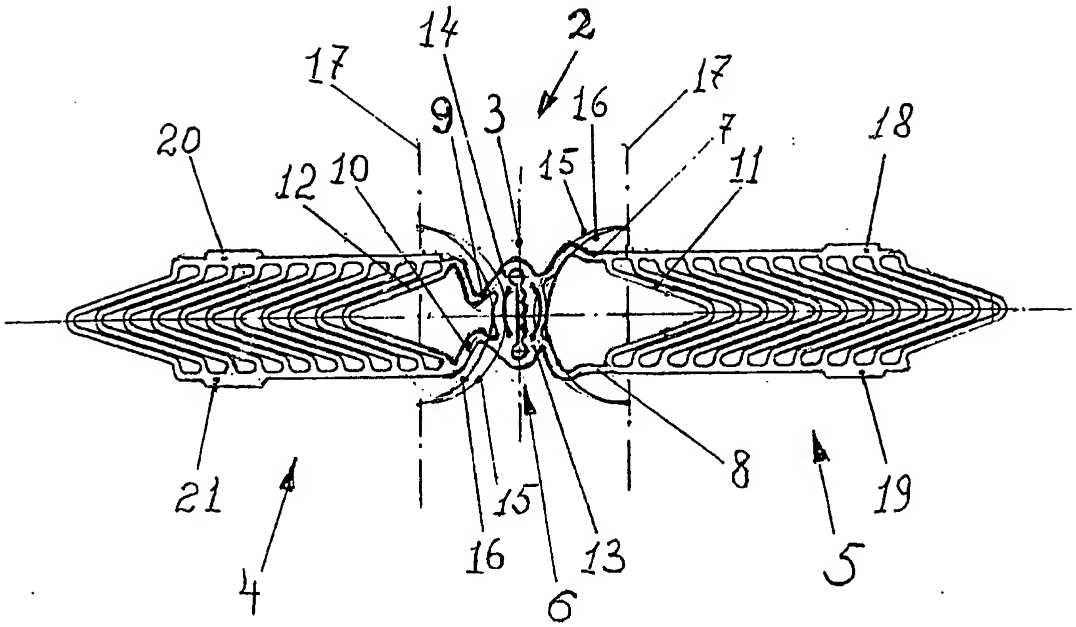
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Fig.3

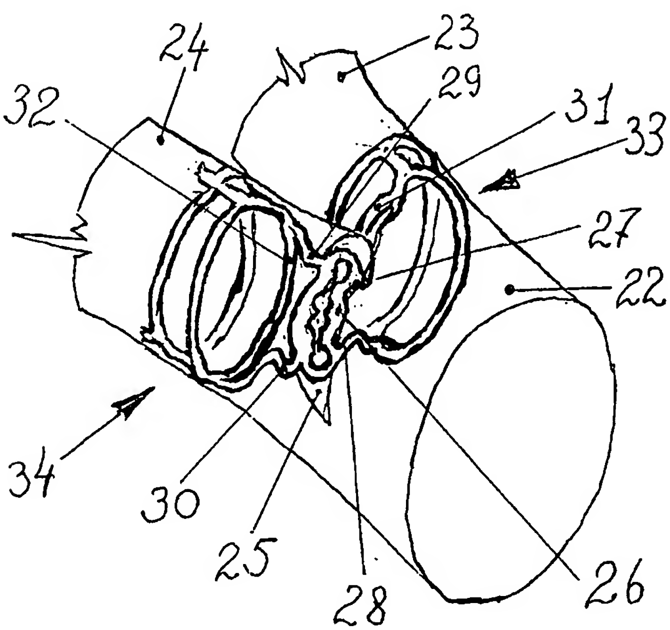
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Fig.4

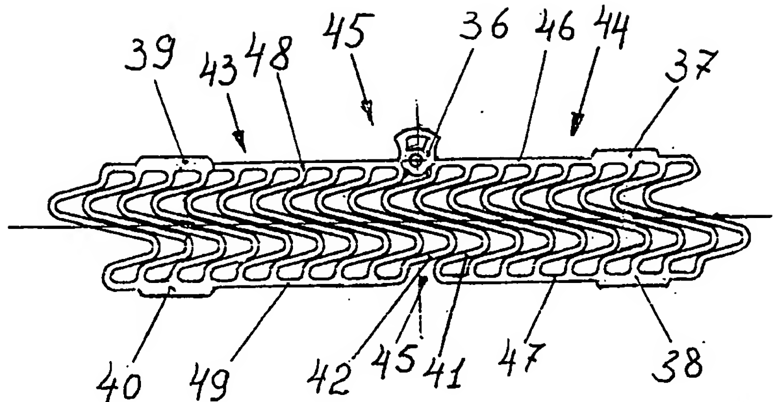

Fig. 5

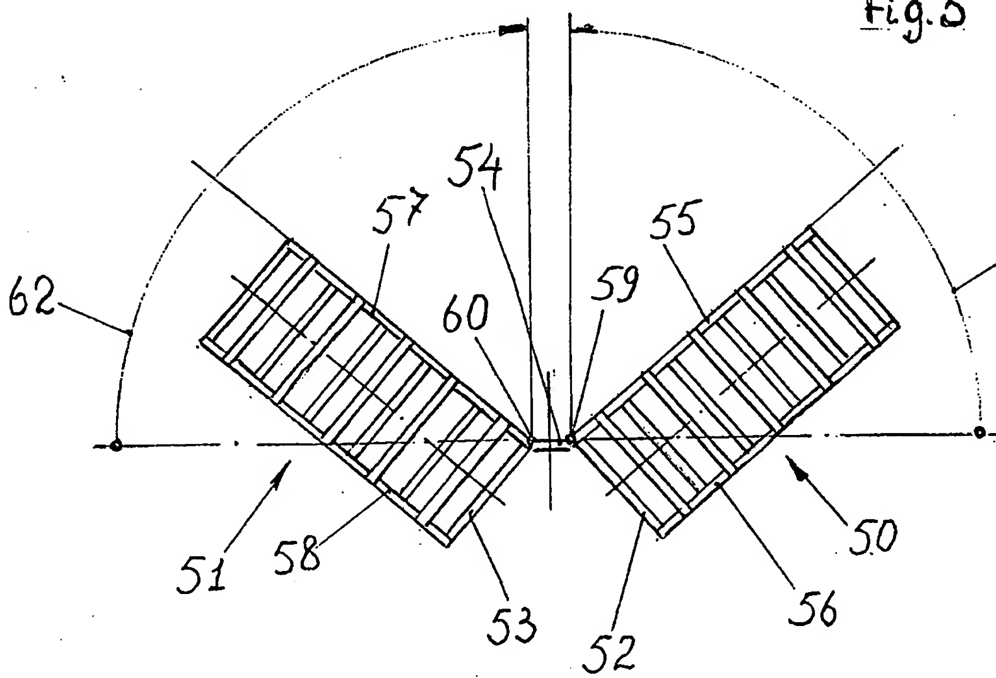

Fig. 6

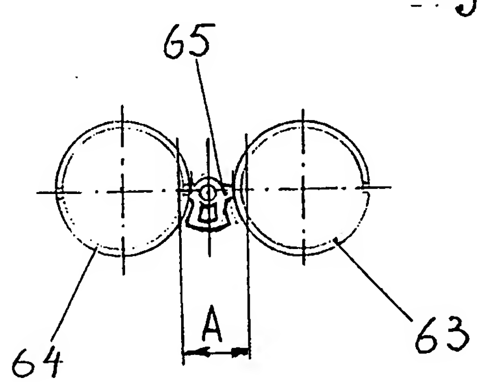

Fig. 7

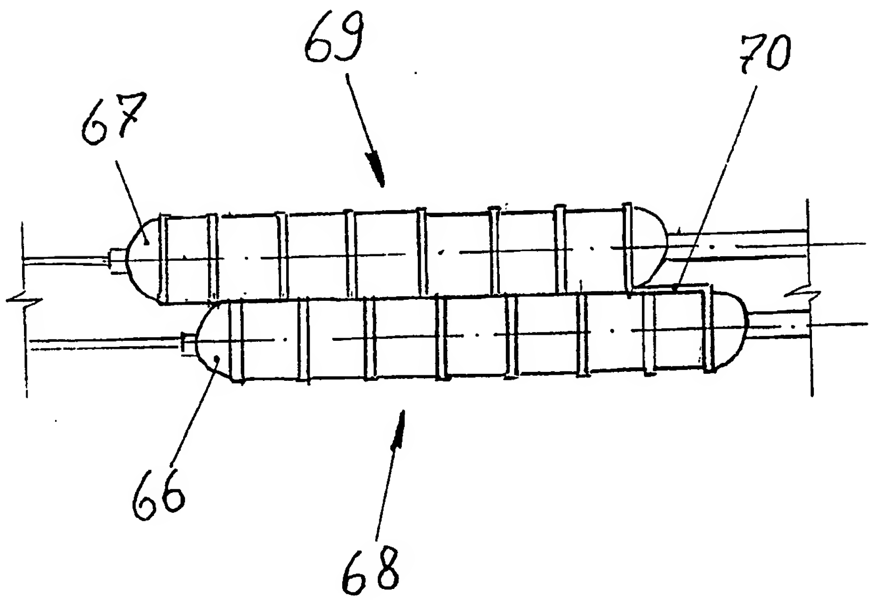

Fig. 8

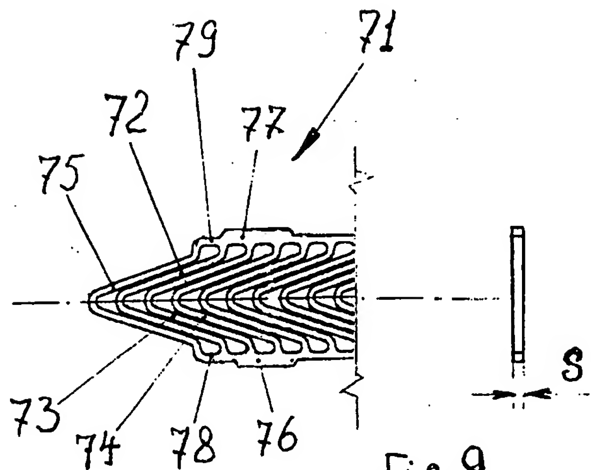

Fig. 9

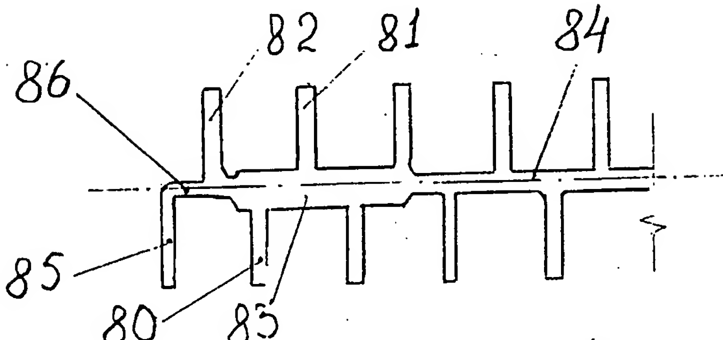

Fig. 10

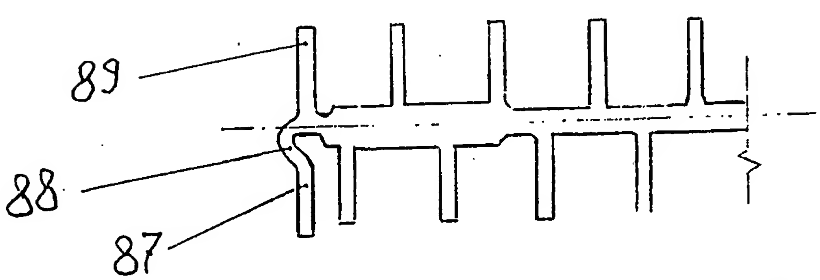

Fig. 11

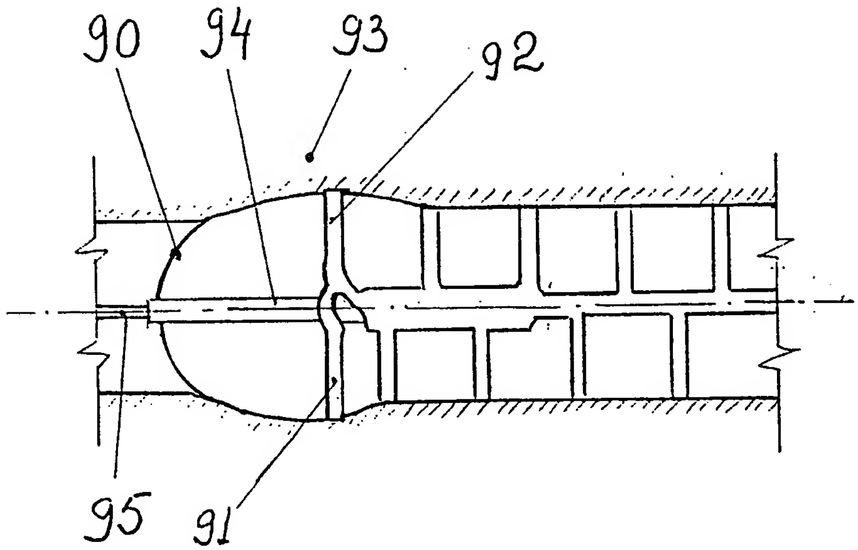

Fig. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL99/00114

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06; A61M 29/00
US CL :606/194. 195; 623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1; 606/194. 195

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,755,771 A (PENN et al) 26 May, 1998, Figs. 1, 2, 5 and 7. The stent can expand more than 5%.	1 --- 3
A	US 5,683,449 A (MARCADE) 04 November 1997, Fig. 2.	1-3
A	US 5,669,924 A (SHAKNOVICH) 23 September 1997, Figs. 41-17.	1-3
A	US 5,836,964 A (RICHTER et al) 17 November 1998, structures of the stent in Fig. 3.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 21 MAY 1999	Date of mailing of the international search report 08 JUN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ALVIN STEWART Telephone No. (703) 305-0277

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL99/00114

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 4 and 5
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.